

REMARKS

In the Office Action mailed on June 4, 2007, the Examiner acknowledged Applicant's Response to Restriction and Election Requirements filed on December 18, 2006; objected to the specification for allegedly failing to provide support for a "member having a convex curved configuration;" rejected claims 36-39 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite; rejected claims 34-45, 47-49, 52-54, and 57-60 under 35 U.S.C. § 102(b) as allegedly being anticipated by O'Connor (U.S. Patent No. 5,450,860); rejected claims 34-49 and 58-60 under 35 U.S.C. § 102(e) as allegedly being anticipated by Fleischman et al. (U.S. Patent No. 6,132,438); rejected claims 34-49, 52-55, 57, 59, and 60 under 35 U.S.C. § 102(e) as allegedly being anticipated by Melvin (U.S. Patent No. 5,957,977); rejected claim 55 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over O'Connor (or claim 57 of Fleischman et al.); rejected claim 46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over O'Connor; and rejected claims 34-49, 52-55, and 57-60 in a nonstatutory obviousness-type double patenting rejection over the claims of U.S. Patent Nos. 6,162,168 and 6,050,936 in view of O'Connor, Fleischman et al., or Melvin.

By this Amendment, Applicant amends claims 34, 36, 40, 41, and 42, and cancels claims 37, 46, 56, 61, and 62. Accordingly, claims 15-36, 38-45, and 47-55, 57-60, and 63-79 are currently pending. Of these claims, claims 15-33, 50, 51, and 63-79 were withdrawn from further consideration by the above-mentioned Response. Of the examined claims, claims 34, 40, 41, and 42 are independent.

As an initial matter, although Applicant does not necessarily agree that claims 50 and 51 do not read on the elected embodiment, as alleged by the Examiner, Applicant

has nonetheless withdrawn claims 50 and 51 from further consideration, in order to expedite the prosecution of this case.

Objection to the Specification

Although Applicant does not necessarily agree that the specification allegedly fails to provide support for a “member having a convex curved configuration,” Applicant has cancelled claim 46, in order to expedite the prosecution of this application. Therefore, the Examiner’s objection has been rendered moot. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the Examiner’s objection to the specification.

35 U.S.C. § 112 Rejection

Although Applicant does not necessarily agree that claims 36-39 are indefinite, as alleged by the Examiner, Applicant has amended claim 36 to include the limitations of now-cancelled claim 37, in order to expedite the prosecution of this application. Amended claim 36 recites a “second connector configured to join the plurality of members.” Accordingly, Applicant respectfully submits that claim 36 does not omit essential structural cooperative relationships between elements and is not a listing of parts. Applicant therefore requests the reconsideration and withdrawal of the Examiner’s Section 112 rejection.

35 U.S.C. § 102(b) Rejection over O’Connor

Applicant respectfully traverses the Examiner’s rejection of claims 34-45, 47-49, 52-54, and 57-60 over O’Connor. Each of amended independent claims 34, 40, 41, and

42 recite a static device comprising, among other things, "a plurality of members positioned on an epicardial surface of [a] heart."

O'Connor discloses a device 10 and method for repairing heart valves. See, for example, Abstract. The O'Connor device 10 includes a ligament 12 having ends 14 and 20. See, for example, Fig. 1. As shown in Fig. 1, some embodiments of ligament 12 may have a first surgical needle 16 attached to end 14 and a second surgical needle 18 attached to end 20. Other embodiments of ligament 12 may have a surgical needle attached to one end and a stop device 72 or 76 attached to the ligament's other end. See, for example, Figs. 16 and 17. O'Connor further discloses the use of mattress sutures 40 /42 placed in tissue 44 of a valve's annulus. See Fig. 3. Mattress sutures 40/42 "act as both markers for the device ends and tie-down sutures to hold the device in place . . . and may include pledgets [48] to protect the tissue from tearing." See col. 7, lines 35-40.

In the Office Action, the Examiner alleges that sutures 40/42 and pledgets 48 correspond to the claimed plurality of members. See Office Action at page 3. Applicant respectfully disagrees with this allegation. Even assuming that sutures 40/42 and pledgets 48 and structure of device 10 meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, O'Connor does not disclose, teach, or otherwise suggest that sutures 40/42 and pledgets 48 are "positioned on an epicardial surface of the heart," as required by independent claims 34, 40, 41, and 42. As shown in Figs. 4-6, sutures 40/42 and pledgets 48 are positioned on an interior surface of a heart (i.e., the annulus of a heart valve), and not an epicardial surface, which includes the outermost surface of the heart. Accordingly, O'Connor fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 34-45, 47-49, 52-54, and 57-60 over O'Connor.

35 U.S.C. § 102(e) Rejection over Fleischman et al.

Applicant respectfully traverses the Examiner's rejection of claims 34-49 and 58-60 over Fleischman et al. Amended independent claim 34 recites a static device including, among other things, a first connector that "is an elongate member that extends across [] at least one [heart] chamber." Each of amended independent claims 40, 41, and 42 recite a static device including, among other things, an elongate connector that extends "across [] at least one [heart] chamber." In other words, each of independent claims 34, 40, 41, and 42 requires at least one elongate connector that extends across a heart chamber.

Fleischman et al. discloses a number of methods and devices for installing stasis reducing means in body tissue. For the purposes of this response, Applicant understands that the Examiner has relied solely on the devices disclosed in Figs. 31A-C and 32B. See Office Action at pages 4-5. If Applicant's understanding is incorrect, the Examiner is invited to telephone the undersigned as soon as possible.

Figures 31A-C of Fleischman et al. show a mechanism which creates a purse-string-like constriction around the interior surface of an atrial appendage 16 or 17. "This arrangement enables pulling of adjacent walls together, thus forming a tightened sack in which the pouch of the appendage is separated from the remainder of the atrium." See col. 13, lines 12-15. The disclosed mechanism may include sutures 126 and expandable anchors 116 (Figs. 31A-C) or 120 (Fig. 32B).

In the Office Action, the Examiner contends that the disclosed sutures 126 correspond to the connector claimed in each of claims 34, 40, 41, and 42. See Office Action at page 4. Applicant respectfully disagrees with this contention. Even assuming that sutures 126 and structure of the Fleischman et al. mechanism can be construed to meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, Fleischman et al. does not disclose, teach, or otherwise suggest that sutures 126 extend across a heart chamber. As shown in Figs. 31A-B, suture 126 merely extends across an atrial appendage 16/17. In addition, as shown in Fig. 32B, suture 126 merely extends through the wall of atrial appendage 16/17. Accordingly, Fleischman et al. fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 34-45, 47-49, 52-54, and 57-60 over Fleischman et al.

#### 35 U.S.C. § 102(e) Rejection over Melvin

Applicant respectfully traverses the Examiner's rejection of 34-49, 52-55, 57, 59, and 60 over Melvin. As mentioned above in the discussion relating to Fleischman et al., each of independent claims 34, 40, 41, and 42 requires at least one elongate connector that extends across a heart chamber.

Melvin discloses a mechanical activator device that includes portions internal to the heart and portions external to the heart. As best shown in Fig. 2 of Melvin, the internal portions include an internal stint 52 that comprises a septal splint 54, a ring 56, and a ring 58. The septal splint 54 contacts and supports the septum outside of the left

ventricle, and includes one or more strands of sutures 55 affixed to a triangularly shaped frame 53. See col. 4, lines 61-66 and col. 5, lines 6-10. The rings 56 and 58 connect to the septal splint 54 and are placed adjacent valves in the left atrium and left ventricle, respectively. The stint 52 connects to the external portion of the device via cords 86 that extend through the heart wall. See col. 8, lines 32-34. Melvin further discloses that the external portion includes a yoke 70 and an activator 74, as shown in, for example, Fig. 5A.

The Examiner contends that each of cords 86, frame 53, ring 58, and septal splint 54 correspond to the connector claimed in each of claims 34, 40, 41, and 42. See Office Action at page 5. Applicant respectfully disagrees with this contention. Even assuming that cords 86, frame 53, ring 58, and septal splint 54 and structure of the Melvin mechanical activator device meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, Melvin does not disclose, teach, or otherwise suggest an elongate connector that extends across a heart chamber, as required by claims 34, 40, 41, and 42.

As shown in Fig. 6, cords 86 do not extend across a heart chamber. Instead, they merely extend through heart wall tissue. Furthermore, the septal splint 54 and its associated frame 53, individually or collectively, do not constitute an elongate member that extends across a heart chamber. Instead, they contact and support the septum outside of the left ventricle. See col. 5, lines 10-15. Lastly, as shown in Fig. 2, ring 58 is not an elongate member that extends across a heart chamber. Accordingly, Melvin fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 34-49, 52-55, 57, 59, and 60 over Melvin.

**35 U.S.C. § 102(b) or § 103(a) Rejection of Claim 55**

In the Office Action, the Examiner rejected claim 55 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over O'Connor (or claim 57 of Fleishman et al.). Even assuming the Examiner's allegations are correct, which Applicant does not concede, claim 55 depends from claim 42 and is allowable for at least the same reasons as claim 42. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the Examiner's rejection of claim 55.

**35 U.S.C. § 103(a) Rejection of Claim 46**

The Examiner rejected claim 46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over O'Connor. The Examiner alleged that it would have been obvious to modify "the implantable device as taught by O'Connor with the member having an inner surface having a convex curved configuration." See Office Action at page 6. Although the cancellation of claim 46 has rendered the Examiner's rejection moot, Applicant nonetheless disagrees with this allegation.

**Double Patenting Rejection**

Applicant respectfully traverses the Examiner's nonstatutory obviousness-type double patenting rejection of claims 34-49, 52-55, and 57-60. Even though Applicant does not necessarily agree with this rejection, Applicant submits herewith a Terminal

Disclaimer to overcome the rejection. The filing of this Terminal Disclaimer in no way manifests an admission by Applicant as to the propriety of the double patenting rejection. See M.P.E.P. § 804.02 citing Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Applicant reserves the right to argue the distinctness or lack of distinctness of the pending claims and the claims of the '168 and '936 patents later, if necessary. Applicant respectfully requests that the Examiner reconsider and withdraw the double-patenting rejection.

### Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and/or drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

If the Examiner wishes to discuss this application, he is invited to contact the undersigned at (202) 408-4221.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

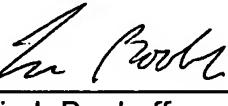
Please grant any extensions of time required to enter this Amendment, and  
charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 14, 2007

By: \_\_\_\_\_

  
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**Attachment: Terminal Disclaimer**